

Information Disclosure Statement

Applicants wish to thank the Examiner for initialing and returning pages 1 through 3 of the Form 1449 mailed on 1 May 2001. However, Applicants further wish to point out that pages 4 and 5 of that Form 1449 (copies attached) were not returned with the Office Action. Applicants respectfully request that the Examiner initial these two attached pages of the Form 1449 and return them with the next communication. Should some of the listed references not be available to the Examiner, Applicants will endeavor to supply copies at the Examiner's request.

**The Rejection of Claims 1 - 36 under 35 USC §103(a) Over JP '721
in view of Guley, and further in view of Reiner or McCabe Has Been Overcome**

Claims 2 - 29 stand rejected under 35 U.S.C. §103(b) as being unpatentable over JP '721 in view of Guley, and further in view of Reiner or McCabe. Applicants respectfully disagree for the reasons that follow.

JP '721 discloses a coated granule that is further coated with "a protecting coating film of a water-soluble polymer (e.g., hydroxypropyl methylcellulose." JP '721 neither discloses nor suggests the use of an anti-grit agent in the outer, "protecting coating film," let alone the combination of an anti-grit agent with a film forming polymer for use in the outer "protecting coating film."

Guley is directed to a sustained release pharmaceutical composition having a compressed core comprised of drug and water soluble polymers and/or water insoluble polymers. This compressed core is then coated with a seal coating, then the seal-coated core is coated with a sugar coating. Guley neither discloses nor suggests the use of: 1) an anti-grit agent in a coating; 2) an anti-grit agent in a coating for granulated drug particles; 3) the combination of an anti-grit agent with a film forming polymer; or 4) the combination of an anti-grit agent with a film forming polymer for use in coating particles.

Therefore, even if one were to combine JP '721 with Guley, the resulting combination would not contain particles coated with an anti-grit agent in combination with a film forming polymer. The Office Action expressly recognizes this fact by providing that "the combination of JP '721 and Guley do not teach the presence of PEG [, an example of an anti-grit agent,] in the outer layer."

Similarly, McCabe is directed to providing taste masking coatings on to pharmaceutical core tablets, as opposed to providing a coating to an individual particle that may subsequently be combined with other particles to form a tablet core. See McCabe, column 2, lines 57 - 60. By

contrast, the present invention is directed to texture masked particles. The particles of the present invention are significantly smaller than conventional tablets, and, for example, may have an average diameter ranging from about 50 microns to about 500 microns. See Specification, page 7, lines 1 – 3. Thus, Applicants respectfully submit that there is neither a disclosure nor a suggestion in McCabe as to the use of its coatings on particles, let alone a disclosure or suggestion as to the process for coating such particles.

In addition, Reiner is directed to providing a lacquer coating onto tablets, and not to providing a coating onto particles. See Reiner, column 2, lines 45- 50 (gum tablets “are ready to be film-coated as if they were normal tablets containing active ingredients.”) Thus, Applicants respectfully submit that there is neither a disclosure nor a suggestion in Reiner as to the use of its coatings on particles, let alone a disclosure or suggestion as to the process for coating such particles.


In sum, because the references fail to disclose or suggest the use of an anti-grit agent, either alone or in combination with a film forming polymer as a texture masking coating on a particle, Applicants respectfully submit that the rejection of independent claim 1 and independent claim 31 under 35 USC §103(a) has been overcome and should be withdrawn.

Applicants further respectfully submit that the rejection of claims 2 – 30, which are dependent upon claim 1 and contain all of its limitations therein, and claims 32 – 36, which are dependent upon claim 31 and contain all of its limitations therein, have been overcome and should be withdrawn for similar reasons.

Conclusion

It is submitted that the foregoing amendments and remarks place the case in condition for allowance. A notice to that effect is earnestly solicited.

Respectfully submitted,
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Att.

- 1) Copies of Pages 4 and 5 of Form 1449

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